Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Evaluation of the effects of green tea consumption compared with black tea on the severity of symptoms, some serum marker, and fatigue, depression and anxiety scores in COVID-19 patients

Protocol summary

Study aim

Determination of the effects of green tea consumption compared to black tea on the severity of symptoms, some serum marker and fatigue, depression and anxiety scores in outpatients with COVID-19

Design

Clinical trial with control group, with parallel groups, no blinding, randomized, phase 2 on 84 patients. Random permutation block method will be used to allocate consumption to the subjects. The website http://www.randomization.com will also be used for randomization.

Settings and conduct

A total of 84 patients with COVID-19 virus confirmed by PCR test referred to a private office or clinic of an infectious disease specialist will be included in the study. Patients in two groups of 42 will be treated with green tea as a drink (3 glasses per day) or black tea (3 glasses per day as a control group).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with COVID-19; Twice positive PCR test;Age over 20 years; Provide written consent to enter the study; Not participating in other clinical trials; no use of other types of herbal teas. Exclusion criteria Pregnancy or breastfeeding; Obesity(body mass index more than30 kg per square meter) History of heart attack or stroke; history of coronary bypass graft or coronary angioplasty, hospitalization history with heart failure; Underlying diseases including chronic hepatitis, cirrhosis and cholestatic liver disease and severe renal failure; Chronic obstructive pulmonary disease or severe pneumonia ;Active gastrointestinal ulcers.

Intervention groups

Intervention group: Patients with covid 19 will consume three cups of green tea daily for four weeks from Heshmat Fooman tea factory . Control group: Patients with covid 19 will consume three cups of black tea daily for four weeks from Heshmat Fooman tea factory .

Main outcome variables

The severity of symptoms؛ some serum marker؛ fatigue, depression, and anxiety scores

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180205038626N8**
Registration date: **2021-05-09, 1400/02/19**
Registration timing: **registered_while_recruiting**

Last update: **2021-05-09, 1400/02/19**
Update count: **0**

Registration date

2021-05-09, 1400/02/19

Registrant information

Name

Zahra Ahmadnia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3361 8177

Email address

zahmadnia@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of green tea consumption compared with black tea on the severity of symptoms, some serum marker, and fatigue, depression and anxiety scores in COVID-19 patients

Public title

Effects of green tea consumption on fatigue, depression and anxiety scores in COVID-19 patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

patients with COVID-19 Twice positive PCR test Age over 20 years Provide written consent to enter the study Not participating in other clinical trials no use of other types of herbal teas

Exclusion criteria:

Pregnancy or breastfeeding Obesity(body mass index more than30 kg per square meter) History of heart attack or stroke, history of coronary bypass graft or coronary angioplasty, hospitalization history with heart failure Underlying diseases including chronic hepatitis, cirrhosis and cholestatic liver disease and severe renal failure Chronic obstructive pulmonary disease or severe pneumonia Active gastrointestinal ulcers

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized permutation block method will be used for allocating consumption of black or green tea to the subjects of the study, and considering quadruple blocks, 21 blocks will be produced for 84 patients. The website http://www.randomization.com will also be utilized for randomization. Moreover, in order to conceal the random allocation procedure, encrypted envelopes with random sequence will be used. Each subject’s envelope will be opened after approving the person`s eligibility for entering the study and Therefore, group A are the patients who receive green tea and group B are the patients that receive black tea.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Technology & Research Vice-chancellor of University; Shahid Siadati St; Namjoo St., Rasht

City

Rasht

Province

Guilan

Postal code

41446-66949

Approval date

2021-03-10, 1399/12/20

Ethics committee reference number

IR.GUMS.REC.1399.670

Health conditions studied

1

Description of health condition studied

Coronavirus disease

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Severity of the viral infection clinical symptoms

Timepoint

At the beginning of the study and 7, 14 and 21 days after tea consumption

Method of measurement

The severity of clinical signs of viral infection will be detected through a respiratory rate more than 24 or a heart rate greater than 125 or the patient requires mechanical ventilation or saturation of peripheral oxygen less than 94% and also based on the patient's laboratory results including D- dimer more than 1000; creatinine phosphokinase twice the normal amount; positive troponin; progressive lymphopenia; ferritin more than 300.

2

Description
Complete blood cell count and diffrential count
Timepoint
At the beginning of the study and one month later
Method of measurement
Cell counter devices

3

Description
C-reactive protein
Timepoint
At the beginning of the study and one month later
Method of measurement
ELISA device

4

Description
Lactate dehydrogenase
Timepoint
At the beginning of the study and one month later
Method of measurement
Biochemical autoanalyzer

5

Description
Creatinine phosphokinase
Timepoint
At the beginning of the study and one month later
Method of measurement
Biochemical autoanalyzer

6

Description
Troponin
Timepoint
At the beginning of the study and one month later
Method of measurement
ELISA device

7

Description
D-dimer
Timepoint
At the beginning of the study and one month later
Method of measurement
ELISA device

8

Description
Ferritin
Timepoint
At the beginning of the study and one month later
Method of measurement
ELISA device

Secondary outcomes

1

Description
Depression score based on Patients Health Questionnaire-9
Timepoint
At the beginning of the study and one month later
Method of measurement
Patients Health Questionnaire-9

2

Description
Scale of fatigue based on Chalder Fatigue Scale (CFQ-11)
Timepoint
At the beginning of the study and one month later
Method of measurement
Chalder Fatigue Scale (CFQ-11) Questionnaire

3

Description
Scale of anxiety based on State-Trait Anxiety Inventory (STAI) Questionnaire
Timepoint
At the beginning of the study and one month later
Method of measurement
State-Trait Anxiety Inventory (STAI) Questionnaire

Intervention groups

1

Description
Intervention group: Patients with Covid 19 will be consumed daily with three cups of green tea equivalent to 12 grams of green tea per day from Heshmat Fooman tea factory for four weeks.
Category
Treatment - Other

2

Description
Control group: Patients with Covid 19 will be consumed daily with three cups of black tea equivalent to 12 grams of black tea per day from Heshmat Fooman tea factory for four weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi hospital
Full name of responsible person
Marjan Mahdavi Roshan

Street address
Razi Educational and Medical Center, Sardar Jangal St.
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Rasht
Province
Guilan
Postal code
4144895655
Phone
+98 13 3355 0028
Email
razi.hospital@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Mohammadreza Naghipour
Street address
Technology & Research Vice-chancellor of University; Shahid Siadati St; Namjoo St., Rasht
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Province
Guilan
Postal code
41446-66949
Phone
+98 13 3333 5821
Email
naghi@gums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht University of Medical Sciences
Proportion provided by this source
80
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

2

Sponsor
Name of organization / entity
Heshmat Tea Factory
Full name of responsible person
Abbas Mohebkhah
Street address
Heshmat tea Factory; km 6 of Qaleh Rudkhan road; Foman
City
Foman
Province
Guilan
Postal code
4358115371
Phone
+98 13 3471 4257
Email
heshmattea@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Heshmat Tea Factory
Proportion provided by this source
20
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Zahra Ahmadnia
Position
Nurse
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Dr. Heshmat Hospital; Bayani St; Mosala Square; Rasht.
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zahmadnia@gums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Marjan Mahdavi Roshan

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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City
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Person responsible for updating data

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Zahra Ahmadnia

Position
Nurse

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
Dr. Heshmat Hospital; Bayani St; Mosala Square; Rasht.

City
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Province
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Postal code
4193955588

Phone
+98 13 3361 8177

Fax

Email
gums.icrc@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Information on the main outcome

When the data will become available and for how long
Access period starts 6 months after the results are published

To whom data/document is available
Researchers working in academic institutions

Under which criteria data/document could be used
Request to receive unidentifiable personal data or other documents

From where data/document is obtainable
Marjan Mahdavi Roshan

What processes are involved for a request to access data/document
By email to Dr.Marjan Mahdavi Roshan

Comments